

SPECTRX INC
Form 10QSB
May 26, 2005

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2005.

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT.

For the transition period from _____

Commission file number: 0-22179

SPECTRX, INC.

(Exact name of small business issuer as specified in its charter)

Delaware

58-2029543

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

**4955 Avalon Ridge Parkway, Suite 300
Norcross, Georgia 30071**

(Address of principal executive offices)

Issuer's telephone number: **(770) 242-8723**

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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As of May 2, 2005, the registrant had outstanding 11,557,437 shares of Common Stock.

Transitional Small Business Disclosure Format. Yes [] No [X]

SPECTRX, INC. AND SUBSIDIARIES

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SPECTRX, INC. AND SUBSIDIARIES

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SPECTRX, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEET

(IN THOUSANDS EXCEPT PAR VALUE)

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ASSETS	December 31, 2004	March 31, 2005 (Unaudited)
CURRENT ASSETS:		
Cash and equivalents	\$247	
		\$26
Accounts receivable		1,336
		674
Inventories		363
		383
Other current assets		203
		164
Total current assets		2,149

1,247

NONCURRENT ASSETS:

Property and equipment, net

573

557

Other assets

83

83

Total noncurrent assets

656

640

TOTAL ASSETS

\$2,805

\$1,887

LIABILITIES AND CAPITAL DEFICIT

CURRENT LIABILITIES:

Accounts payable	\$566
	\$731
Accrued liabilities	491
	645
Redeemable convertible preferred stock and accrued dividends in default	1,436
	1,436
Redeemable convertible preferred stock, current portion	1,711
	1,711
Advance payable	381
	381
Total current liabilities	4,585
	4,904

LONG TERM LIABILITIES:

Redeemable convertible preferred stock and accrued dividends

1,634

1,686

Dividends payable - series A

281

372

TOTAL LIABILITIES

6,500

6,962

COMMITMENTS & CONTINGENCIES

CAPITAL DEFICIT:

Series A preferred stock (Liquidation preference \$7,330)

4,559

4,559

Common stock

12

Additional paid-in capital	
	52,688
	52,688
Treasury stock, at cost	
	(104)
	(104)
Deferred compensation	
	(42)
	(38)
Accumulated deficit	
	(60,808)
	(62,192)
TOTAL CAPITAL DEFICIT	
	(3,695)
	(5,075)
Total liabilities and capital deficit	
	\$2,805
	\$1,887

The accompanying notes are an integral part of these consolidated statements.

SPECTRX, INC. AND SUBSIDIARIES

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2005
(In Thousands Except Per Share Data)

	Three Months Ended	
	March 31,	
	2004	2005
REVENUE:		
NET REVENUE	\$125	\$369
COSTS AND EXPENSES:		
Cost of product sales	286	393
Research and development	939	664
Sales and marketing	163	150
General and administrative	325	363
	1,713	1,570
Operating loss	(1,588)	(1,201)
INTEREST INCOME (EXPENSE), net	(903)	(40)
NET LOSS	(2,491)	(1,241)
PREFERRED STOCK DIVIDENDS	(73)	(143)
DEEMED DIVIDEND ON SERIES A PREFERRED	(4,970)	0
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(7,534)	\$(1,384)
BASIC AND DILUTED NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(0.66)	\$(0.12)
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	11,372	11,557

The accompanying notes are an integral part of these consolidated statements.

SPECTRX, INC. AND SUBSIDIARIES

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In Thousands)

Three Months Ended
March 31,

2004

2005

CASH FLOWS FROM OPERATING ACTIVITIES: Net loss

\$(2,491)

\$(1,241)

Adjustments to reconcile net loss to net cash used in operating activities

Depreciation and amortization

115

26

Loss on retirement of assets

Amortization of deferred compensation

10

4

Issuance of options and warrants

791

0

Changes in operating assets and liabilities:

Accounts receivable

14

(38)

Inventories

(65)

10

(20)

Other current assets

320

39

Accounts payable

105

165

Accrued liabilities

109

154

Total adjustments

1,399

355

Net cash used in operating activities

(1,092)

(886)

CASH FLOWS FROM INVESTING ACTIVITIES:

Additions to property and equipment

(34)

(35)

Net proceeds from sale of BiliCheck assets

655

700

Net cash provided by (used in) investing activities

621

CASH FLOWS FROM FINANCING ACTIVITIES:

Issuance of common stock, net of issuance costs

18

0

Issuance of series A preferred stock and warrants

6,330

0

Dividends paid on redeemable convertible preferred stock

(300)

0

Net cash provided by financing activities

6,048

0

NET INCREASE IN CASH AND CASH EQUIVALENTS

5,577

(221)

CASH AND EQUIVALENTS, beginning of period

389

247

CASH AND EQUIVALENTS, end of period

\$5,966

\$26

The accompanying notes are an integral part of these consolidated statements.

SPECTRX, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The unaudited interim financial statements included herein have been prepared by SpectRx, Inc. These statements reflect adjustments, all of which are of a normal, recurring nature, and which are, in the opinion of management, necessary to present fairly our financial position as of March 31, 2005, results of operations for the three months ended March 31, 2004 and 2005, and cash flows for the three months ended March 31, 2004 and 2005. The results of operations for the three months ended March 31, 2004 and 2005 are not necessarily indicative of the results for a full fiscal year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. Preparing financial statements requires our management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results could differ from those estimates. Our accounting policies continue unchanged from December 31, 2004. These financial statements should be read in conjunction with the financial statements and notes thereto included in our annual report on Form 10-KSB for the year ended December 31, 2004.

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced net losses since our inception, and, as of March 31, 2005, we had an accumulated deficit of approximately \$62.2 million. To date, we have engaged primarily in research and development efforts. We first generated revenue from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our products. Our development efforts may not result in commercially viable products, and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance, and we may not ever achieve levels of revenue to sustain further development costs and support ongoing operations or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect operating losses to continue through at least 2005 as we continue to expend substantial resources to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

In addition, a portion of our revenues and profits are expected to be derived from (a) earnout that we will receive from Respironics, Inc. ("Respironics") resulting from sales of the *BiliChek* infant jaundice products and (b) from the insulin delivery products developed by our subsidiary, Sterling Medivations, Inc. ("Sterling"). The earnout that we expect to receive from Respironics and profits from Sterling products depend on sales of these respective products. We intend to market our insulin delivery products directly to distributors and other customers. Respironics may not be able to sell sufficient volumes of the infant jaundice products to generate substantial royalties for us.

Going Concern

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. At March 31, 2004, our current liabilities exceeded current assets by approximately \$3.7 million and we have a capital deficit due principally to our recurring losses from operations. We have initiated litigation against Abbott Laboratories, Inc. ("Abbott"), asserting substantial damages and are withholding payment due under our redeemable preferred stock agreement. As a consequence we are in default on payments due under our settlement with Abbott regarding our redeemable preferred stock agreement. These factors raise substantial doubt about our ability to continue as a going concern. Additional debt or equity financing will be required for us to continue as a going concern. The consolidated financial statements do not include any adjustments that might be required from the outcome of this uncertainty. We currently plan to raise additional funds through financing our accounts receivable and seeking additional debt funding secured by our potential *BiliChek* earnout.

If additional funds do not become available, we have plans to curtail operations by reducing discretionary spending and staffing to levels to those supportable by available funding. Under certain circumstances, we may have to curtail our SimpleChoice operations and only pursue activities for which we have external financial support, such as the NIAAA contract and the National Cancer Institute funding. Management is working to obtain additional funds and believes those funds along with funds from sales and earnout revenues may be sufficient to support planned operations through December 31, 2005. However, there can be no assurance that we will be able to raise additional funds on acceptable terms, or at all, or achieve planned sales volumes.

Reclassification

Certain amounts in the 2004 cash flow statement have been reclassified to reflect the Gain on sale of Bilichek product line as investing activities rather than operating activities.

2. SIGNIFICANT ACCOUNTING POLICIES

Our significant accounting policies are included in the audited financial statements and notes thereto for the year ended December 31, 2004 included in our annual report on Form 10-KSB filed with the Securities and Exchange Commission ("SEC").

3. STOCK BASED COMPENSATION

We use the intrinsic value method for valuing our awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. FASB Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," amends the disclosure provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation," and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure in the summary of significant accounting policies of the effects of an entity's policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Our pro forma information follows (in thousands, except per share data):

	Three Months Ended March 31	
	2004	2005
Net loss attributable to common stockholders, as reported	\$(7,534)	\$(1,384)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects		

Deduct: Total stock-based employee compensation expense determined under fair value based method of all awards,
net of related tax effects

(80)

(41)

Pro forma net loss

\$(7,614)

\$(1,425)

Loss per share:

Basic & diluted, as reported

(\$0.66)

\$(0.12)

Basic & diluted, pro forma

(\$0.67)

\$(0.12)

4. LITIGATION

In January 2003, we announced that we were initiating actions required to terminate our research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. We are withholding payment due in connection with the redemption of the shares of our preferred stock held by Abbott in connection with our claims under the agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of our preferred stock was required to be redeemed on December 30, 2002 at \$10 per share. We asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. We reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock redeemed, with the 162,500 shares to be redeemed on December 30, 2002 at \$10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately \$0.7 million, \$1.3 million, \$1.8 million and \$1.9 million for 2003, 2004, 2005 and 2006, respectively. We paid \$400,000 and \$300,000 to Abbott pursuant to the settlement, respectively, during 2003 and in the first quarter of 2004. Under the settlement, neither party admitted any liability or wrongdoing.

On July 15, 2004, Abbott sent us a letter notifying that we were in default on two separate payments due in 2004 and demanded payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent a letter notifying we were in default on an additional payment due in 2004 and demanded payment. We again responded that we expected to continue to seek to resolve the patent issues and renegotiate the payment terms.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to the dispute over intellectual property issues. We are represented in this matter under a contingency fee arrangement. In connection with the dispute and litigation, we have not paid \$1.4 million of the amount due in 2004. This amount has been shown as a current liability.

On October 14, 2004, Respiroics notified us that an allegation of patent infringement related to the *BiliChek* product had been made and that it believed that this matter was subject to the indemnification provision of our asset sale agreement which could require us to pay a portion of the costs related to certain infringement of intellectual property brought within two years of the closing date. On April 20, 2005, we entered into a settlement agreement with Respiroics resolving the matter. In connection with the settlement and in exchange for Respiroics agreeing to pay the earnout payments early due for 2004, Respiroics will withhold approximately \$275,000 of earnout payments due for 2006. We will reflect this settlement in the financial statements for the three months ended June 30, 2005. No additional claims are expected under the indemnification clause because more than two years have passed since the closing date of the *BiliChek* asset sale.

5. STOCKHOLDERS' EQUITY

Preferred Stock

In January 1997, authorized 5,000,000 shares of preferred stock with a \$.001 par value. The board of directors has the authority to issue these shares and to fix dividends, voting and conversion rights, redemption provisions, liquidation

preferences, and other rights and restrictions.

In November 1999, the board of directors has designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. Dividends are payable annually in cash or additional shares of the preferred stock at the rate of 6% per annum. During the years ended December 31, 2003 and 2004, we accrued dividends in the form of shares redeemable convertible preferred stock of \$299,000 and \$278,000, respectively. The shares of preferred stock, together with any accrued but unpaid dividends, are convertible into shares of common stock at the greater of \$9.39 per share or the average of the closing sales price for 15 days prior and 15 days subsequent to the conversion and automatically convert on December 31, 2004 at the then conversion rate. The shares were mandatorily redeemable at \$10 per share, plus accrued but unpaid dividends, at the later of September 30, 2002 or 60 days subsequent to the date upon which we give notice to Abbott of Abbott's right to redeem the shares. The shares have a liquidation preference of \$10 per share, plus all accrued but unpaid dividends.

In November 1999, Abbott subscribed to 525,000 shares of redeemable convertible preferred stock for consideration of \$5,250,000 of which \$2,750,000 was received in November 1999 and \$2,500,000 was received in January 2000.

In September 2001, we entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its Redeemable Convertible Preferred Stock plus the related accrued but unpaid dividends. On December 31, 2004, these were automatically converted into 139,007 shares of our common stock at \$9.39 per share.

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of the remaining redeemable convertible preferred stock eligible for redemption. On March 7, 2003, we reached a settlement with Abbott regarding their disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock held by Abbott redeemed by us. Abbott had previously elected to have 425,000 shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at \$10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, we agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay accrued dividends as to such shares. We paid \$400,000 and \$300,000 to Abbott during 2003 and 2004, respectively. Our yearly financial obligations to Abbott under the agreement are approximately \$1.4 million, \$1.8 million and \$1.9 million for 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

Dividends are accrued on the non-redeemable preferred stock at a rate of 6% per year and are included in the short-term portion and long-term portion of redeemable preferred stock in the accompanying consolidated balance sheets.

We were in negotiations with Abbott from early 2003 through February of 2005 regarding the patent issue and the payments of "outstanding accrued dividends" and "redemption" under the settlement. Abbott notified us that we were in default on four separate payments due in 2004 and demanded payment.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to our dispute over intellectual property issues (see Note 4). We are represented in this matter under a contingency fee arrangement. In connection with this matter, we have not paid \$1.4 million of the amounts due in 2004.

Series A Convertible Preferred Stock

We currently have outstanding 488,669 shares of series A convertible preferred stock, having a stated value of \$15.00 per share, held by 28 holders as of December 31, 2004. The holders of the series A convertible preferred stock are entitled to receive quarterly, at the end of each calendar quarter, commencing on and after March 26, 2006, out of funds legally available therefor, dividends per share at the per annum rate of \$0.75 per share. As of March 31, 2005,

we have accrued \$372,000 of dividends payable.

Each share of series A convertible preferred stock is convertible into the number of shares of common stock equal to the quotient obtained by dividing the sum of (i) \$15.00 (as adjusted for changes in the series A convertible preferred stock by stock split, stock dividend, or the like occurring after March 26, 2004), referred to as the invested amount, plus (ii) all declared or accrued but unpaid dividends on such shares of series A convertible preferred stock, by the conversion price per share. The current per share conversion price is \$1.50. The conversion price is subject to adjustment under certain circumstances to protect the holders of series A convertible preferred stock from dilution relative to certain issuances of common shares, or securities convertible into or exercisable for common shares. Subject to certain exceptions, if we issue common shares, or such other securities, at a price per share less than the then effective conversion price, the conversion price will be adjusted to equal such lower per share consideration.

The holders of the series A convertible preferred stock have the right of first refusal to purchase their pro-rata shares of any new securities, as defined in the certificate of designations governing the series A convertible preferred stock, that we may, from time to time, propose to sell and issue.

Issuing the series A convertible preferred stock triggered recognition of the value attributable to the beneficial conversion feature of the series A convertible preferred stock, which is deemed to be a dividend if the effective conversion price of the preferred stock is below market at the time of the transaction. We recognized a deemed dividend in the first quarter of 2004 of approximately \$4.6 million recognizing the difference between issuance price and market price at issuance for the convertible instrument as a deemed dividend and increased stockholders' equity in the same amount, so that there was no net effect on the capital deficit.

In connection with the series A convertible preferred stock issuance, noteholders, at our request, exchanged \$1.0 million of notes payable into series A convertible preferred stock.

Stock Options

Our 1995 Stock Plan (the "Plan"), as amended, provides a total of 1,928,572 shares of common stock, of which a total of 1,638,221 shares remain available. The Plan allows the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options is determined by our board of directors, but incentive stock options must be granted at an exercise price equal to the fair market value of our common stock as of the grant date. Options generally become exercisable over four years and expire ten years from the date of grant. At March 31, 2005, options to purchase 64,632 shares of common stock were available for future grant under the Plan. Currently up for vote, our plans are to extend this stock option plan by 10 years and also to increase the total number of available options, subject to approval from the stockholders.

In January 2002, we assumed the Sterling Medivations 2000 Stock Option Plan, with authorized shares of 93,765. No options have been exercised under this plan. At December 31, 2004, 6,090 options were outstanding under this plan, and 87,675 shares were still available for future grant, subject to the provisions of the Agreement and Plan of Merger between us and Sterling Medivations.

6. LOSS PER COMMON SHARE

Loss per common share is computed using SFAS No. 128, "Earnings per Share." SFAS No. 128 established standards for the computation, presentation and disclosure of earnings per share. Basic loss per share amounts are computed by dividing the net loss by the weighted average number of common shares outstanding during the periods. Dilutive earnings per share calculations include the potential exercise of outstanding stock options, warrants and convertible securities. The effects of stock options, warrants and convertible securities have not been included in our 2004 and 2003 loss per share computations as their effect would have been anti-dilutive. Potential common shares totaling 12,967,522, which consist of the common stock underlying all outstanding stock options, preferred stock and

warrants, are considered to be anti-dilutive for the three months ended March 31, 2005.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

Statements in this report which express "belief," "anticipation" or "expectation" as well as other statements which are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those set forth under "Risk Factors" in this "Management's Discussion and Analysis or Plan of Operations" and elsewhere in this report. Examples of these uncertainties and risks include, but are not limited to:

- access to sufficient debt or equity capital to meet our operating and financial needs;
- the effectiveness and ultimate market acceptance of our products;
- whether our products in development will prove safe, feasible and effective;
- whether and when we or any potential strategic partners will obtain approval from the FDA and corresponding foreign agencies;
- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;
- the lack of immediate alternate sources of supply for some critical components of our products;
- our patent and intellectual property position;
- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines; and
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products.

The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this report.

OVERVIEW

We were incorporated on October 27, 1992, and since that date, we raised capital through the sale of preferred stock, issuances of debt securities, public and private sales of common stock, funding from collaborative arrangements and sales of assets. Following our initial funding in early 1993, we immediately began research and development activities with the objective of commercializing less invasive diagnostic, screening and monitoring products. As part of our initial business strategy, we established arrangements with leading medical device companies for the development, commercialization and introduction of some of our products. We developed collaborative arrangements with Abbott Laboratories, Inc., Welch Allyn, Inc. and Respironics, Inc. for our continuous glucose monitoring, cervical cancer detection and BiliChek products, respectively. In 2003, we sold our BiliChek business to our collaborative partner, Respironics, and agreed to terminate our collaborative relationships with Abbott for our continuous glucose monitoring product. In 2002, we and Welch Allyn terminated our collaborative relationship for our cervical cancer detection product. In addition, we have a collaborative agreement with Roche related to a diabetes detection product, although there is currently little development activity with regard to this product, and we expect no revenue from this product in the foreseeable future. We are pursuing a collaborative partner for our glucose monitoring product, and we may seek to establish strategic relationships with other leading companies for the development, commercialization, and introduction of additional products, such as our cervical cancer detection product, if we believe that is the best path to commercialization for those products.

In December 2001, we acquired 100% of the common stock of Sterling Medivations, Inc. (doing business as SimpleChoice), a company formed for the purpose of developing and marketing insulin-delivery products.

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This

industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception, and, as of March 31, 2005, we have an accumulated deficit of about \$62.2 million. To date, we have engaged primarily in research and development efforts. We first generated revenues from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our products. Our development efforts may not result in commercially viable products, and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance, and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue through at least May 2006 as we continue to expend substantial resources to introduce our SimpleChoice product line, further the development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

Our product revenues to date have been limited. For 2004, a majority of our revenues came from our SimpleChoice insulin delivery product and research contract revenue. We expect that the majority of our revenue in 2005 will be derived from sales of our SimpleChoice insulin delivery products. Our other products for glucose monitoring and cervical cancer detection are still in development.

We currently sell our insulin delivery products to distributors, which then distribute our products, resulting in revenues from distributor sales. The channels for sales of our glucose monitoring and cervical cancer detection products are not currently established. The earnout that we expect to receive from Respironics depend on sales of the applicable products. We, or our collaborative partner, if we secure one, may not be able to sell sufficient volumes of our products to generate substantial revenues or profits for us.

CRITICAL ACCOUNTING POLICIES

Our material accounting policies, which we believe are the most critical to an investor's understanding of our financial results and condition, are discussed below. Because we are still early in our enterprise development, the number of these policies requiring explanation are limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

Currently, our policies that could require critical management judgment are in the areas of revenue recognition, reserves for accounts receivable and inventory valuation.

Revenue Recognition: We recognize revenue from sales of products or services upon shipment of products or delivery of services. We also recognize milestone revenue from collaborative partners when a milestone has been accomplished or when we, and our partner, agree that a milestone has been reached.

Reserve for Accounts Receivable: We estimate losses from the inability of our customers to make required payments and periodically review the payment history of each of our customers, as well as their financial condition, and revise our reserves as a result.

Inventory Valuation: Inventories are valued at the lower of cost or market value and have been reduced by an allowance for excess and obsolete inventories.

RESULTS OF OPERATIONS

COMPARISON OF THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004.

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Net loss available to common stockholders was \$1.4 million during the three months ended March 31, 2005 as compared to a net loss available to common stockholders of \$7.6 million for the same period in 2004. Included in the 2004 results was a non-cash deemed dividend of approximately \$4.9 million to reflect the accounting treatment of the issuance of shares of our series A convertible preferred stock with a conversion price below market price at the time of issuance.

Net loss was \$1.2 million during the three months ended March 2005, as compared to a net loss of \$2.5 million for the same period in 2004. Product revenue increased to \$369,000 from \$125,000 primarily due to the increase in the SimpleChoice revenue. Gross loss decreased from \$161,000 in 2004 to a loss of \$24,000 in 2005. Operating expense was \$250,000 less in the first quarter of 2005 than the same period in 2004. Operating loss in the first quarter of 2005 as a result was \$1.2 million as compared to \$1.6 million in 2004.

Revenue. Product revenue increased to \$369,000 for the quarter ended March 31, 2005 from \$125,000 for the same period in 2004. Product revenue is higher for the 2005 quarter than for the comparable period in 2004 due to the increase in SimpleChoice sales.

Cost of Sales. Cost of sales increased to \$393,000 for the three months ended March 31, 2005 from \$286,000 for the same period in 2004. The increase was primarily due to SimpleChoice revenue. Included in the cost of sales is \$165,000 of overheads pertaining to our operations department.

Research and Development Expenses. Research and development expenses decreased to approximately \$664,000 for the three months ended March 31, 2005 compared to \$939,000 for the same period in 2004. The decrease was due to reduced expenses in glucose monitoring and SimpleChoice research and development.

Sales and Marketing Expenses. Sales and marketing expenses decreased slightly to \$150,000 during the three months ended March 31, 2005 from \$163,000 for the same period in 2004. Marketing expenses are expected to increase in the future as we continue to market and sell our SimpleChoice product line.

General and Administrative Expenses. General and administrative expenses increased to \$363,000 during the three months ended March 31, 2005 compared to \$325,000 for the same period in 2004. General and administrative expenses are expected to increase in the future with increases in SimpleChoice revenue.

Net Interest and Other Expense. Net interest and other expense decreased to \$40,000 for the three months ended March 31, 2005 as compared to expense of \$903,000 for the same period in 2004. The decrease is primarily due to the recognition of interest expense on the issuance of warrants related to bridge loans in the first quarter of 2004.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception primarily through private sales of debt and private and public sales of our equity securities. At March 31, 2005, we had cash of approximately \$26,000 and negative working capital of approximately \$3.7 million.

In August 2002, Abbott notified us that it intended to redeem the \$4.25 million of redeemable convertible preferred stock eligible to be redeemed. Under a settlement agreement related to the termination of our collaborative arrangement with Abbott, we agreed with Abbott to redeem the 425,000 shares of preferred stock on an extended schedule through 2006, but are not currently doing so due to on going litigation.

Our major cash flows in the quarter ended March 31, 2005 consisted of cash out-flows of \$886,000 from operations (including \$1.2 million of operating loss and the purchase of \$35,000 of property and equipment and net proceeds of \$700,000 from sale of Bilicheck assets.

We have historically also received funds from milestones and reimbursements from our collaborative partners. We are currently seeking a collaborative partner for our glucose monitoring technology. Until we reach an agreement with a new partner, we expect no such milestones or reimbursements. We have been successful in securing grants to support some of our programs, including grants totaling over \$2 million, to be spent over 2004 and 2005, from the NCI for our cervical cancer program. In March 2003, we sold the assets related to the *BiliChek* products, as non-core assets, for \$4.0 million of cash at closing, an additional \$1.0 million upon completion of some component replacement engineering work, which we received in November 2003, and up to \$6.25 million in earnout payments based upon the future performance of the business as conducted by the buyer, Respironics. We received \$655,000 of earnout in the first quarter of 2004 for performance during 2003 and we have received approximately \$1.0 million of earnout in 2005 for performance during 2004. We received \$700,000 of this earnout in the first quarter of 2005 and \$331,000 of earnout was received in April 2005.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements in addition to those sources. Assuming we are successful in financing our accounts receivable, we believe our existing and available capital resources will be sufficient to satisfy our funding requirements through December 2005, excluding any amounts due on redeemable convertible preferred stock during the year. We need to secure a collaborative partner to move forward with our continuous glucose program and will also need funding in addition to that provided by grants to complete our pivotal trials for our cervical cancer product in a timely fashion. We are evaluating various options to further reduce our cash requirements by operating our programs at a reduced rate, as well as options to raise additional funds, including loans using certain assets as collateral.

Substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required United States and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure of our collaborative partners to fund our development expenditures, or our inability to obtain capital through other sources, would have a material adverse effect on our business, financial condition and results of operations.

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued a revised Statement of Financial Accounting Standards (SFAS) No. 123R, "Shares Based Payment." The revised SFAS No. 123R requires that the fair value of stock options be recorded in the results of operations beginning no later than January 1, 2006. Upon adoption of the revised standard, prior awards are charged to expense under the prior rules, and awards after adoption are charged to expense under the revised rules. We have not determined the effect of the new standard on our earnings; however, expense under the new standard could be somewhat higher. The effect of adopting the new rules on reported diluted earnings per share is dependent on the number of options granted in the future; the terms of those awards and their fair values, and therefore, the effect on diluted earnings per share could change. We expect to adopt the revised rules on January 1, 2006.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements; no special purpose entities; nor activities that include non-exchange-traded contracts accounted for at fair value.

Impairment of Long-Lived Assets

We evaluate our long-lived assets for impairment annually or when events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. We evaluate the recoverability of long-lived assets not held for sale by measuring the carrying amount of the assets against the estimated undiscounted future cash flows associated with them. We have experienced delays in expanding the line of products which are covered by the patents, underlying the intangibles. While our projection for the sales of these products over the life of these patents is

significant, the range of outcomes regarding the product introductions is highly subjective, such that the full recoverability of the carrying value of the intangible assets is questionable. Although management believes that the SimpleChoice products continue to have substantial potential for the foreseeable future, the range of estimates of the undiscounted cash flows required us to treat these assets as impaired for accounting purposes and we recorded an impairment charge of \$3,211,000 for the period ended December 31, 2004.

RISK FACTORS

The following risk factors should be considered carefully in addition to the other information presented in this report. This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, the following:

ALTHOUGH IT IS LIKELY THAT WE WILL BE REQUIRED TO RAISE ADDITIONAL FUNDS WITHIN THE NEXT SIX MONTHS, THERE IS NO ASSURANCE THAT SUCH FUNDS CAN BE RAISED ON TERMS THAT WE WOULD FIND ACCEPTABLE, OR AT ALL.

Management believes that the funds from expected SimpleChoice working capital financing (accounts receivable and inventory), sales, research and development reimbursement, contracts and royalty income will not be sufficient to support planned operations beyond December 31, 2005. Management has implemented operating actions to reduce cash requirements and is evaluating various options to raise additional funds, including pursuing loans using certain assets as collateral. In addition, if we experience delays, are unable to finance our SimpleChoice working capital requirements, are unable to meet our sales projections or if we are unable to satisfactorily resolve our differences with Abbott regarding the schedule of payments for the redemption of the redeemable preferred shares, we will need to raise an even greater amount of additional funds. Any required additional funding may not be available on terms attractive to us or at all.

IF WE CANNOT OBTAIN ADDITIONAL FUNDS OR ACHIEVE PROFITABILITY, WE MAY NOT BE ABLE TO CONTINUE AS A GOING CONCERN.

Because we must execute our plans to launch our remaining products in our SimpleChoice product line and grow our revenues to sufficiently higher levels to generate profits and cash flow from operations, there exists substantial doubt about our ability to continue as a going concern. Management believes funds from expected SimpleChoice working capital financing (accounts receivable and inventory), sales, research and development reimbursement, contracts and royalty income will not be sufficient to support planned operations through November 30, 2005. Therefore it will be necessary to raise additional funds. If we have delays or are unable to meet our financial plan, we will have to raise additional funds before November 30, 2005. There can be no assurance that we will be able to raise these additional funds. If we do not secure additional funding when needed, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of all of our products. Even if we obtain additional funding, we will need to achieve profitability thereafter.

Our management has implemented reductions in operating expenditures and reductions in development activities. We are managing the development of our cervical cancer detection technology with the support of contracts and grants we have secured. We are managing the development of our glucose monitoring and ISF technology through a contract with the NIAAA while we also look for a collaborative partner to fund the development of our glucose monitoring technology. However, there can be no assurance that we will be able to successfully implement or continue these plans or that we will be able to do so without significantly harming our business, financial condition or results of operations.

WE DO NOT HAVE A LONG OPERATING HISTORY, WHICH MAKES IT DIFFICULT FOR YOU TO EVALUATE OUR BUSINESS.

Because limited historical information is available on our revenue trends and operations, it will be difficult for you to evaluate our business. Our historical financial information also includes the sale of our *BiliChek* product line in March of 2003. Our prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasing intense competition and a high failure rate.

WE HAVE A HISTORY OF LOSSES, AND WE EXPECT LOSSES TO CONTINUE.

We have never been profitable, and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to launch the SimpleChoice product line, to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations, and conduct further research and development. To date, we have engaged primarily in research and development efforts. The further development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was about \$62.2 million at March 31, 2005.

IF WE CANNOT OBTAIN ADDITIONAL FUNDS WHEN NEEDED, WE WILL NOT BE ABLE TO IMPLEMENT OUR BUSINESS PLAN.

We will require substantial additional capital to develop our products, including completing product testing and clinical trials, obtaining all required regulatory approvals and clearances, beginning and scaling up manufacturing, and marketing our products. We have historically funded a significant portion of our activities through collaborative partners. We are seeking a collaborative partner for our glucose monitoring technology and are seeking separate funding for our cervical cancer program. Any failure to find a collaborative partner to fund our operations and capital expenditures, or our inability to obtain capital through other sources, would limit our ability to grow and operate as planned. Even if we do enter into an agreement with a collaborative partner, the obligations of a collaborative partner to fund our expenditures will be largely discretionary and will depend on a number of factors, including our ability to meet specified milestones in the development and testing of the relevant product. We may not be able to meet these milestones, or our collaborative partner may not continue to fund our expenditures.

We bear responsibility for all aspects of our SimpleChoice product line and our cervical cancer product, which are not being developed with a collaborative partner. In addition to any funds that may be provided by collaborative partners, we will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements. We believe that our existing capital resources, and the funding from various sources will be sufficient to satisfy our funding requirements through November 2005, but may not be sufficient to fund our planned operations to the point of commercial introduction of our glucose monitoring products, our cervical cancer detection product or our full line of diabetes products. Any failure to agree on a collaborative arrangement or to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of one or more of our development initiatives. Any required additional funding may not be available on terms attractive to us, or at all. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited. Any additional equity financing may be dilutive to stockholders, and debt and certain types of equity financing, if available, may involve restrictive covenants or other provisions that would limit how we conduct our business or finance our operations.

WE ARE NO LONGER LISTED ON A NASDAQ MARKET, WHICH MAY AFFECT OUR ABILITY TO OBTAIN ADDITIONAL FUNDS WHEN NEEDED AND THE LIQUIDITY AND VALUE OF OUR COMMON STOCK.

The Nasdaq National Market and SmallCap Market have minimum listing requirements. In December 2002, we applied for and moved to the Nasdaq SmallCap Market because we could not continue to meet the National Market listing requirements. A key requirement is the level of stockholders' equity. At June 30, 2003, our stockholders' equity

was below the minimum Nasdaq requirements and, as a result, our stock was delisted from the SmallCap Market. Our stock is now listed on the OTC Bulletin Board, which does not have similar listing requirements. As a result, our ability to raise additional capital may be impacted and the liquidity and value of our common stock may be impaired.

OUR SIMPLECHOICE PRODUCT LINE HAS A DIFFERENT FOCUS THAN OUR NON-INVASIVE PRODUCTS, AND WE WILL BE REQUIRED TO DEVELOP NEW CAPABILITIES TO SUCCESSFULLY MANAGE THESE OPERATIONS.

Prior to our acquisition of the SimpleChoice product line, it did not have revenues or significant assets. The SimpleChoice product line is also significantly different from our historical product line, which focuses on non-invasive and minimally invasive products. We shipped small quantities of our first SimpleChoice products to be introduced to the market beginning in 2003. SimpleChoice's future business will depend on our ability to develop more fully various functions that will enable it to operate as planned, including manufacturing, marketing, and distribution capabilities. There can be no assurance that we, or our subsidiary doing business as SimpleChoice, will be able to successfully develop or implement these functions.

OUR ABILITY TO SELL OUR PRODUCTS IS CONTROLLED BY GOVERNMENT REGULATIONS, AND WE MAY NOT BE ABLE TO OBTAIN ANY NECESSARY CLEARANCES OR APPROVALS.

The design, manufacturing, labeling, distribution and marketing of medical device products are subject to extensive and rigorous government regulation, which can be expensive and uncertain and can cause lengthy delays before we can begin selling our products.

IN THE UNITED STATES, THE FOOD AND DRUG ADMINISTRATION'S ACTIONS COULD DELAY OR PREVENT OUR ABILITY TO SELL OUR PRODUCTS, WHICH WOULD ADVERSELY AFFECT OUR GROWTH AND STRATEGY PLANS.

In order for us to market our products in the United States, we must obtain clearance or approval from the FDA. We cannot be sure:

- that we, or any collaborative partner, will make timely filings with the FDA;
- that the FDA will act favorably or quickly on these submissions;
- that we will not be required to submit additional information or perform additional clinical studies;
- that we would not be required to submit an application for premarket approval, rather than a 510(k) premarket notification submission as described below; or
- that other significant difficulties and costs will not be encountered to obtain FDA clearance or approval.

The SimpleChoice products to date have been introduced subject to 510(k) premarket notification submissions. There have been 27 510(k) premarket notification submissions related to SimpleChoice approved by the FDA through March 31, 2005.

The premarket approval process is more rigorous and lengthier than the 510(k) clearance process for premarket notifications; it can take several years from initial filing and require the submission of extensive supporting data and clinical information. For example, Roche, as part of our collaborative agreement, had previously filed a premarket notification for our diabetes detection product, which was withdrawn when the FDA indicated that this product should be submitted for premarket approval, including submission of clinical study data. We do not have any premarket notifications or premarket approval applications pending, but our cervical cancer detection product and, we believe our glucose monitoring products will require submission of applications for premarket approval.

The FDA may impose strict labeling or other requirements as a condition of its clearance or approval, any of which could limit our ability to market our products. Further, if we wish to modify a product after FDA clearance of a

premarket notification or approval of a premarket approval application, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals will be required from the FDA. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies or submit to the more rigorous and lengthier premarket approval process, could result in a significant delay in bringing our products to market and substantial additional research and other expenditures. Similarly, any labeling or other conditions or restrictions imposed by the FDA on the marketing of our products could hinder our ability to effectively market our products. Any of the above actions by the FDA could delay or prevent altogether our ability to market and distribute our products. Further, there may be new FDA policies or changes in FDA policies that could be adverse to us.

IN FOREIGN COUNTRIES, INCLUDING EUROPEAN COUNTRIES, WE ARE ALSO SUBJECT TO GOVERNMENT REGULATION, WHICH COULD DELAY OR PREVENT OUR ABILITY TO SELL OUR PRODUCTS IN THOSE JURISDICTIONS.

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required to market our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, we must maintain ISO 13485:1996 certification and CE mark certification, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to receive or maintain ISO 13485:1996 certification or CE mark certification or other international regulatory approvals would prevent us from selling in some countries in the European Union. We must upgrade to ISO 13485:2003 by June 2006 to retain the CE mark.

EVEN IF WE OBTAIN CLEARANCE OR APPROVAL TO SELL OUR PRODUCTS, WE ARE SUBJECT TO ONGOING REQUIREMENTS AND INSPECTIONS THAT COULD LEAD TO THE RESTRICTION, SUSPENSION OR REVOCATION OF OUR CLEARANCE.

We, as well as our potential collaborative partners, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements will be strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

OUR SUCCESS LARGELY DEPENDS ON OUR ABILITY TO OBTAIN AND PROTECT THE PROPRIETARY INFORMATION ON WHICH WE BASE OUR PRODUCTS.

Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others patents and patent applications necessary to develop our products. If any of our patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our products were to be limited, our ability to continue to manufacture and market our products

could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

We have been issued, or have rights to, 39 U.S. patents (including those under license). In addition, we have filed for, or have rights to, 25 U.S. patents (including those under license) that are still pending. There are additional international patents and pending applications. One or more of the patents we hold directly or license from third parties, including those for the disposable components to be used with our glucose monitoring, infant jaundice and insulin delivery products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the United States Patent and Trademark Office may institute interference proceedings. The defense and prosecution of intellectual property suits, Patent and Trademark Office proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the proceedings could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from selling our products in some or all markets. We may not be able to reach a satisfactory settlement of any dispute by licensing necessary patents or other intellectual property. Even if we reached a settlement, the settlement process may be expensive and time consuming, and the terms of the settlement may require us to pay substantial royalties. An adverse determination in a judicial or administrative proceeding or the failure to obtain a necessary license could prevent us from manufacturing and selling our products.

WE MAY NOT BE ABLE TO GENERATE SUFFICIENT SALES REVENUES TO SUSTAIN OUR GROWTH AND STRATEGY PLANS.

We expect that the majority of our revenues in 2005 will come from sales of our new SimpleChoice diabetes product line, which has just been launched and some of which is still in development. We sold our BiliChek product line in 2003 and will not have continuing revenue from that source other than future earnout payments. Although we received a payment for earnout of about \$1.0 million for 2004, there can be no assurance of additional payments. Our ability to collect additional earnout payments from the BiliChek product line depends on Respironics' efforts in conducting that business. Our glucose monitoring product in development depends on finding a new partner and the collaborative partner's ability to generate sales of our products, which should provide us with revenue. We may not be able to successfully commercialize the products we are developing. Even if we do, we, together with any collaborative partners with respect to products being jointly developed, may not be able to sell sufficient volumes of our products to generate profits for us.

WE ARE DEVELOPING OUR CURRENT PRODUCT LINES INDEPENDENTLY FROM ANY COLLABORATIVE PARTNERS, WHICH WILL REQUIRE US TO ACCESS ADDITIONAL CAPITAL AND TO DEVELOP ADDITIONAL SKILLS TO PRODUCE, MARKET AND DISTRIBUTE THESE PRODUCTS.

We are independently finishing development, building up production capacity, launching, marketing and distributing our SimpleChoice line of products. These activities require additional resources and capital that we will need to secure. There is no assurance that we will be able to raise sufficient capital or attract and retain skilled personnel to

enable us to finish development, launch and market these products. Thus, there can be no assurance that we will be able to commercialize all, or any, of these products.

BECAUSE OUR PRODUCTS, WHICH USE DIFFERENT TECHNOLOGY OR APPLY TECHNOLOGY IN MORE INNOVATIVE WAYS THAN OTHER MEDICAL DEVICES, ARE OR WILL BE NEW TO THE MARKET, WE MAY NOT BE SUCCESSFUL IN LAUNCHING OUR PRODUCTS AND OUR OPERATIONS AND GROWTH WOULD BE ADVERSELY AFFECTED.

Our products are based on new methods of glucose monitoring and cervical cancer detection and new methods of delivery for our diabetes products. If our products do not achieve significant market acceptance, our sales will be limited and our financial condition will suffer. Physicians and individuals may not recommend or use our products unless they determine that these products are an attractive alternative to current tests that have a long history of safe and effective use. To date, our products have been used by only a limited number of people, and few independent studies regarding our products have been published. The lack of independent studies limits the ability of doctors or consumers to compare our products to conventional products.

IF WE ARE UNABLE TO COMPETE EFFECTIVELY IN THE HIGHLY COMPETITIVE MEDICAL DEVICE INDUSTRY, OUR FUTURE GROWTH AND OPERATING RESULTS WILL SUFFER.

The medical device industry in general, and the markets in which we expect to offer products in particular, are intensely competitive. Many of our competitors have substantially greater financial, research, technical, manufacturing, marketing and distribution resources than we do and have greater name recognition and lengthier operating histories in the health care industry. We may not be able to effectively compete against these and other competitors. A number of competitors offer insulin infusion disposable products and a number of competitors are currently marketing traditional glucose monitors. These disposable products and monitors are widely accepted in the health care industry and have a long history of accurate and effective use. Further, if our products are not available at competitive prices, health care administrators who are subject to increasing pressures to reduce costs may not elect to purchase them. Also, a number of companies have announced that they are developing products that permit non-invasive and less invasive glucose monitoring. Accordingly, competition in this area is expected to increase.

Furthermore, our competitors may succeed in developing, either before or after the development and commercialization of our products, devices and technologies that permit more efficient, less expensive non-invasive and less invasive glucose monitoring, insulin delivery, or cancer detection. It is also possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of diabetes or otherwise render our products obsolete.

WE HAVE LITTLE MANUFACTURING EXPERIENCE, WHICH COULD LIMIT OUR GROWTH.

We do not have manufacturing experience that would enable us to make products in the volumes that would be necessary for us to achieve significant commercial sales, and we rely upon our suppliers. In addition, we may not be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs, in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and maintain our manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. To date, our manufacturing activities have included our former *BiliChek* and *BiliCal* products, as well as the diabetes detection product on a limited scale. We are having our initial product offerings in the SimpleChoice insulin delivery area manufactured by a third party. We may decide to manufacture these products ourselves in the future or may decide to manufacture products that are currently under development in this market segment. Companies often encounter difficulties in scaling up production, including problems involving production yield, quality control and assurance, and shortages of qualified personnel.

SINCE WE RELY ON SOLE SOURCE SUPPLIERS FOR SEVERAL OF OUR PRODUCTS, ANY FAILURE OF THOSE SUPPLIERS TO PERFORM WOULD HURT OUR OPERATIONS.

Several of the components used in our products are available from only one supplier, and substitutes for these components could not be obtained easily or would require substantial modifications to our products. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. For our products which require premarket approval, the inclusion of substitute components could require us to qualify the new supplier with the appropriate government regulatory authorities. Alternatively, for our products which qualify for premarket notification, the substitute components must meet our product specifications.

Since we are relying on third party manufacturing for our initial product offerings in the SimpleChoice product line, we are dependent upon those parties for product supply. Any delay in initiating production or scaling production to higher volumes could result in delays of product introduction, or create lower availability of product than our expectations. These delays could lead to lower revenue achievement and additional cash requirements for us.

OUR LIMITED MARKETING AND SALES EXPERIENCE MAKES OUR SIMPLECHOICE REVENUE UNCERTAIN.

We are responsible for marketing our SimpleChoice product line. We have relatively limited experience in marketing or selling medical device products and only have a five person marketing and sales staff. In order to successfully continue to market and sell our products, we must either develop a marketing and sales force or expand our arrangements with third parties to market and sell our products. We may not be able to successfully develop an effective marketing and sales force, and we may not be able to enter into and maintain marketing and sales agreements with third parties on acceptable terms, if at all. If we develop our own marketing and sales capabilities, we will compete with other companies that have experienced and well-funded marketing and sales operations. If we enter into a marketing arrangement with a third party, any revenues we would receive will be dependent on this third party, and we will likely be required to pay a sales commission or similar compensation to this party. The efforts of these third parties for the marketing and sale of our products may not be successful.

BECAUSE WE OPERATE IN AN INDUSTRY WITH SIGNIFICANT PRODUCT LIABILITY RISK, AND WE HAVE NOT SPECIFICALLY INSURED AGAINST THIS RISK, WE MAY BE SUBJECT TO SUBSTANTIAL CLAIMS AGAINST OUR PRODUCTS.

The development, manufacture and sale of medical products entail significant risks of product liability claims. We may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale of our products. A successful product liability claim or series of claims brought against us that results in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. In addition, product liability insurance is expensive and may not be available to us on acceptable terms, if at all.

THE AVAILABILITY OF THIRD-PARTY REIMBURSEMENT FOR OUR PRODUCTS IS UNCERTAIN, WHICH MAY LIMIT CONSUMER USE AND THE MARKET FOR OUR PRODUCTS.

In the United States and elsewhere, sales of medical products are dependent, in part, on the ability of consumers of these products to obtain reimbursement for all or a portion of their cost from third-party payors, such as government and private insurance plans. Any inability of patients, hospitals, physicians and other users of our products to obtain sufficient reimbursement from third-party payors for our products, or adverse changes in relevant governmental policies or the policies of private third-party payors regarding reimbursement for these products, could limit our ability to sell our products on a competitive basis. We are unable to predict what changes will be made in the

reimbursement methods used by third-party health care payors. Moreover, third-party payors are increasingly challenging the prices charged for medical products and services, and some health care providers are gradually adopting a managed care system in which the providers contract to provide comprehensive health care services for a fixed cost per person. Patients, hospitals and physicians may not be able to justify the use of our products by the attendant cost savings and clinical benefits that we believe will be derived from the use of our products, and therefore may not be able to obtain third-party reimbursement.

Reimbursement and health care payment systems in international markets vary significantly by country and include both government sponsored health care and private insurance. We may not be able to obtain approvals for reimbursement from these international third-party payors in a timely manner, if at all. Any failure to receive international reimbursement approvals could have an adverse effect on market acceptance of our products in the international markets in which approvals are sought.

OUR SUCCESS DEPENDS ON OUR ABILITY TO ATTRACT AND RETAIN SCIENTIFIC, TECHNICAL, MANAGERIAL AND FINANCE PERSONNEL.

Our ability to operate successfully and manage our future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, as well as our ability to attract and retain additional highly qualified personnel in these fields. We may not be able to attract and retain key employees when necessary, which would limit our operations and growth. None of our key employees have an employment contract with us, nor are any of these employees, except our chief executive officer, covered by key person or similar insurance. In addition, if we are able to successfully develop and commercialize our products, we will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers.

ADJUSTMENTS TO THE CONVERSION PRICE FOR OUR SERIES A CONVERTIBLE PREFERRED STOCK AND THE EXERCISE PRICE FOR CERTAIN OF OUR WARRANTS WILL DILUTE THE OWNERSHIP INTERESTS OF OUR EXISTING STOCKHOLDERS.

On March 26, 2004, we entered into agreements with investors to raise capital in a private placement of our series A convertible preferred stock and warrants. As a result of this private placement transaction, there are 488,669 shares of our series A convertible preferred stock outstanding convertible into 4,886,690 shares of our common stock at a conversion price of \$1.50 per share, plus warrants exercisable for 2,443,345 shares of our common stock at an exercise price of \$1.65 per share and warrants exercisable for 2,443,345 shares of our common stock at an exercise price of \$2.25 per share. The conversion price for the series A convertible preferred stock and the exercise price for the warrants may be lowered under certain price adjustment provisions in the certificate of designations relating to the series A convertible preferred stock and the warrants if we issue common stock at a per share price below the then conversion price for the series A convertible preferred stock.

Subject to certain exceptions, if we issue shares of our common stock, or securities convertible into or exercisable for shares of our common stock, at a price per share less than the then effective conversion price for the series A convertible preferred stock, the conversion price for the series A convertible preferred stock will be adjusted to equal such lower per share consideration, the exercise price for the warrants with the \$1.65 exercise price will be adjusted to equal such lower per share consideration, and the exercise price for the warrants with the \$2.25 exercise price will be adjusted to equal 125% of such lower per share consideration. A reduction in the conversion price for the series A convertible preferred stock and the exercise price for the warrants will result in the issuance of a significant number of additional shares of our common stock upon conversion of the series A convertible preferred stock and the exercise of the warrants, respectively. The downward adjustment of the conversion price for the series A convertible preferred stock and the exercise price for these warrants would cause us to recognize an additional charge for the adjustment and result in dilution in the value of the shares of our outstanding common stock and the voting power represented thereby.

WE ARE SIGNIFICANTLY INFLUENCED BY OUR DIRECTORS, EXECUTIVE OFFICERS AND THEIR AFFILIATED ENTITIES.

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 20% of our outstanding common stock as of May 2, 2005. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers and other business combination transactions.

ITEM 3. CONTROLS AND PROCEDURES

We maintain a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer has concluded that our disclosure controls and procedures were effective as of March 31, 2005.

There have been no changes in our internal controls over financial reporting that occurred during the quarter ended March 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In January 2003, we announced that we had given notice that we were initiating actions required to terminate our research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. We further announced that we were withholding payment due in connection with the redemption of the shares of our preferred stock held by Abbott as an offset to claims that have also been made by us under our agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of our preferred stock were required to be redeemed on December 30, 2002 at \$10 per share. We also announced that we had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. We filed a Form 8-K on March 10, 2003, announcing that we had reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at \$10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately \$1.4 million, \$1.8 million and \$1.9 million for 2004, 2005 and 2006, respectively. We paid \$400,000 and \$300,000 to Abbott pursuant to the settlement, respectively, during 2003 and 2004. Under the settlement, neither party admitted any liability or wrongdoing.

We were in negotiations with Abbott from early 2003 through February of 2005 regarding the patent issue described in Note 4 to the Financial Statements and the payments of "outstanding accrued dividends" and "redemption" under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent us a letter notifying us that we were in

default on an additional payment due in 2004 and demanding payment. We again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to our dispute over intellectual property issues. We are represented in this matter under a contingency fee arrangement. In connection with the dispute and litigation, we have not made the four payments totaling \$1.4 million due in 2004. On April 6, 2005, Abbott notified us that it considered us in default on a total of \$1.4 million.

On October 14, 2004, Respiroics notified us that an allegation of patent infringement related to the *BiliChek* product had been made and that it believed that this matter was subject to the indemnification provision of our asset sale agreement which could require us to pay a portion of the costs related to certain infringement of intellectual property brought within two years of the closing date. On April 20, 2005 Respiroics and SpectRx entered into a settlement agreement resolving the matter. In connection with the settlement and in exchange for Respiroics agreeing to pay the earnout payments early due for 2004, Respiroics will withhold approximately \$275,000 of earnout payments due for 2006.

On February 22, 2005, we received a letter of patent infringement from ICU Medical related to our SimpleChoice product line. We received the letter shortly after meeting with the CEO of ICU Medical, Inc. to discuss partnering opportunities related to SimpleChoice. Management believes that the infringement claim is without merit and has provided information to ICU Medical, Inc. that supports our position.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of the remaining redeemable convertible preferred stock eligible for redemption. On March 7, 2003, we reached a settlement with Abbott regarding their disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock held by Abbott redeemed by us. Abbott had previously elected to have 425,000 shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at \$10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, we agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay accrued dividends as to such shares. We paid \$400,000 and \$300,000 to Abbott during 2003 and 2004, respectively.

We were in negotiations with Abbott from early 2003 through February of 2005 regarding the patent issue described in Note 4 to the Financial Statements and the payments of "outstanding accrued dividends" and "redemption" under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two additional payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to our dispute over intellectual property issues. We are represented in this matter under a contingency fee arrangement. In connection with the dispute and litigation, we have not made the four payments totaling \$1.4 million due in 2004. On April 6, 2005, Abbott notified us that it considered us in default on a total of \$1.4 million.

ITEM 6. EXHIBITS

EXHIBIT INDEX

EXHIBIT

<u>Exhibit Number</u>	<u>Exhibit Description</u>
31	<u>Rule 13a-14(a)/15d-14(a) Certification</u>
32	<u>Section 1350 Certification</u>

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SPECTRX, INC.

/s/ MARK A. SAMUELS

By: Mark A. Samuels
Chairman and Chief Executive Officer

Date: 05/25/2005